In the Drawings:

Please amend FIG. 10 pursuant to the amended figure provided.

REMARKS

Introductory Comments

Claims 1-15 and 17-90 are pending in the present application. Claims 17, 18, 38, 39, 69, 70, 80, 81, 89, and 90 have been withdrawn in light of the previous restriction requirement. Claims 19, 20, 40, 41, 49, 52, 54-57, 59, 62, 64-66, 68-73, 76-78, 82, and 85-87 have been amended. FIG. 10 of the drawings has been amended. Reconsideration of the application is respectfully requested.

October 24, 2006 Office Action

Information Disclosure Statement

The October 24 Office action asserts that the information disclosure statement filed by Applicant on August 24 is defective because no copy of PCT/US03/10950 was found. It is respectfully submitted that this conclusion is in err.

Applicant specifically listed the international search report of PCT/US03/10950 on the IDS (Applicant has referred to this by the acronym "ISR," representative of International Search Report). Applicant has confirmed on PAIR that a copy of the international search report of PCT/US03/10950 was received by the Office and can find no basis as to why the submission was somehow defective.

Applicant has previously requested consideration of this international search report and related search reports by the Examiner involving counterpart and related applications to the instant application. Nevertheless, Applicant respectfully submits that a copy of published application PCT/US03/10950, along with its corresponding search report, is provided with the instant IDS to overcome those issues perceived to render the previous submission defective. It is respectfully requested that the Examiner consider those materials listed on the IDS form.

Objections to the Specification

The drawings are objected to under 35 U.S.C. § 132 (a) as allegedly introducing new matter. This objection has been addressed by the instant amendments to FIG. 10, but is respectfully traversed as to its merits.

In response to the Examiner's original objection to the drawings, which was that the drawings did not show the augments being mounted to the acetabular cavity within a hip bone, Applicant amended the drawings to reflect augments fastened around the acetabular cavity within a hip bone. The October 24 Office action objects to the revised drawings on new matter grounds by alleging that the scale of the augment features is new matter. The case law is quite clear that unless otherwise noted, drawings are not presumed to be at a particular scale or limited to particular dimensions.[1,2] Nevertheless, proposed drawing amendments to FIG. 10 are submitted in an effort to further prosecution of the application.

The Office action also raises an objection to the claim terminology utilized by Applicant to precisely claim his invention. Particularly, the Office action states that no antecedent basis is found in the specification as filed for the claim term "curb," citing to 37 C.F.R. § 1.75 (d)(1) and M.P.E.P. § 608.01 (o). While the case law is similarly clear that Applicant is not required to use only those words found in the written description for his claims[3], Applicant has amended the claims to recite the original terminology of

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[1] See *Go Medical Industries Pty., Ltd. v. Inmed Corp.*, --- F.3d ----, 2006 WL 3041853, *5 (Fed. Cir. 2006) ("[P]atent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt, Inc. v. Avia Group. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000); see also *In re Wright*, 569 F.2d 1124, 1127 (C.C.P.A. 1977) ("Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.")).

[2] See also *In re Reynolds*, 443 F.2d 384, 389 (C.C.P.A. 1971) ("We realize that a patent drawing does not have to be to any particular scale.").

[3] See *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed. Cir. 1995) ("The prior application need not describe the claimed subject matter in exactly the same terms as used in the claims...."). See also Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991), and *In re Wertheim*, 541 F.2d 257, 265 (C.C.P.A. 1976) ("The PTO has done nothing more than to argue lack of literal support, which is not enough. ... '[T]he invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112.' The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient."). See also *Schoenhaus v. Genesco, Inc.*, 440 F.3d 1354, 1358 (Fed. Cir. 2006) ("The patentee is free to act as his own lexicographer, and may set forth any special definitions of the claim terms in the patent specification or file history, either expressly or impliedly. *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004)").

"raised augment" in lieu of "curb" to obviate this ground of objection and further prosecution.

Finally, the drawings are objected to as allegedly failing to show "all" of the constraining augments adapted to be fastened to the "acetabular cavity within a hip bone" or "positionable about a femoral member."[4] There is an ambiguity within this ground of rejection as Applicant is uncertain whether "all" refers to all of the augments within a single drawing or whether all refers to all of the augments within all of the drawings. In either case, this ground of objection is respectfully traversed.

For at least two reasons this ground of objection is in err. First, if only two augments are utilized for stability purposes, FIG. 10 clearly shows *all* two of the constraining augments being adapted to be fastened around the "acetabular cavity within a hip bone" or "positionable about a femoral member." For this reason alone, Applicant has shown the objection to the drawings is without merit. Second, there is no requirement that the all of the augments shown in all of the drawings are adaptable to mounting around the acetabulum. If this were the case, it would effectively prohibit Applicant from showing one of his exemplary embodiments where the augments are adapted to be mounted to the acetabular cup. Thus, this ground of objection is in err and should be withdrawn.

Finally, Applicant has amended the claims to omit the "adapted" language.

In light of the foregoing, the objections to the drawings and specification are improper and should be withdrawn, particularly in light of Applicant's amendments to further prosecution. Reconsideration and withdrawal of the objections to the drawings and specification are respectfully requested.

35 U.S.C. §102 Rejections

Claims 27-36, 40-42, 46, 47, 51, 54-66, and 71-78 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by German Patent Publication No. DE 197 16 051 to Kluber ("Kluber"). This ground of rejection with respect to claims 27-36, 40-42, 46, 47, 51, 54-66, and 71-78 is respectfully traversed.

[4] Office action, p. 3.

Claim 27 recites a hip prosthesis comprising: (a) an acetabular cup assembly to be fastened to a patient's pelvis; (b) a femoral stem to be fastened to the patient's femur, the femoral stem including a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling; and (c) a semiannular augment to be mounted to a distal end of the acetabular cup assembly, adjacent to the ball component, wherein the semiannular augment assists in stabilizing the ball joint type coupling between the acetabular cup assembly and the femoral stem by temporarily increasing the height of a portion of the rim of the acetabular cup, while enabling rotational and angular movement between the acetabular cup assembly and the femoral stem, the semiannular augment being formed from an augment material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials, and wherein the semiannular augment includes at least *one integrated fastener*.

No indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the retaining ring includes an integrated fastener. In fact, Kluber only discloses rings that do not have integral fasteners. The absence of a comparison of the pending claims against the disclosure of Kluber provides Applicant little opportunity to confront the inaccurate conclusions of the Office action. It is not Applicant's burden to guess the bases for the conclusions recited in the Office action, particularly where no citations were provided as to Kluber, and Applicant declines to do so.

Claim 28, which depends from claim 27, further requires the fastener is formed from a fastener material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials. No indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the retaining ring includes an integrated fastener made from one of these materials.

Claim 29, which depends from claim 28, further requires the fastener material includes at least one, or an equivalent, of: a poly-L-lactic acid material or collagen. Again, no indication is provided in the Office action as to where in Kluber it is

purportedly disclosed that the retaining ring includes an integrated fastener that includes one of these materials.

Claim 30, which depends from claim 28, further requires the fastener comprises at least one of: (a) a screw; (b) a snap; (c) a clip; (d) a keyway; (e) a dowel; and (f) a rivet. No indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the retaining ring includes an integrated fastener comprising a screw, a snap, a clip, a keyway, a dowel or a rivet.

Claim 32, which depends from claim 31, further requires the extra cellular matrices (ECMs) of the augment material include at least one of: porcine small intestine submucosa (SIS); xenogeneic small intestine submucosa (xSIS); urinary bladder submucosa (UBS); laminated intestinal submucosa; and glutaraldehyde-treated bovine pericardium (GLBP). No indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the integral augment material includes extra cellular matrices that includes one of the foregoing components.

Claim 33, which depends from claim 27, further requires a distal surface of the semiannular augment is contoured to approximate the shape of a portion of the neck of the femoral component. No indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the distal surface of the semiannular augment is contoured to approximate the shape of a portion of the neck of the femoral component.

Claim 34, which depends from claim 27, further requires the semiannular augment is positioned on the anterior/superior portion of the acetabular cup assembly. No indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the semiannular augment is positioned on the anterior/superior portion of the acetabular cup assembly.

Claim 35, which depends from claim 27, further requires the semiannular augment includes a contoured, radially inner surface to approximate an outer surface of the ball of the femoral stem. No indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the semiannular augment includes a contoured, radially inner surface to approximate an outer surface of the ball of the femoral stem.

Claim 36, which depends from claim 27, further requires the contoured, radially inner surface of the semiannular augment is substantially semi-spherically shaped. No

indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the contoured, radially inner surface of the semiannular augment is substantially semi-spherically shaped.

Analogous recitations could also be made by Applicant for claims 40-42, 46, 47, 51, 54-66, and 71-78 pointing out the absence of any express basis in the Office action for rejecting these claims. Applicant has omitted these analogous recitations for purposes of brevity, but it is to be understood that the same deficiencies exist as to the grounds of rejection concerning these claims.

The Office action does specifically allege, however, that Kluber discloses, with respect to claim 54, a plurality of individual constraining curbs. In summary fashion, the Office action cites to the two differing ring thicknesses disclosed in Kluber for the proposition that Kluber discloses multiple rings. But no portion from Kluber discloses that multiple rings with differing thicknesses would be included in a kit. Claim 54 requires a kit having multiple rings, whereas Kluber discloses a single ring that may be interchangeable with another ring of a differing thickness. In other words, at no time does the disclosure of Kluber objectively reflect a realization or expectation that multiple rings could be utilized at the same time. Particularly, Kluber fails to disclose multiple luxation rings being mounted approximate an acetabular cup. Thus, Kluber does not anticipate claim 54.

Reconsideration and withdrawal of the rejections of record for claims 27-36, 40-42, 46, 47, 51, 54-66, and 71-78 are respectfully requested.

35 U.S.C. §103 Rejections

Claims 1-15, 19-26, 37, 43-45, 48-50, 52, 53, 67, 68, 79, and 82-88 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious in view of German Patent Publication No. DE 197 16 051 to Kluber ("Kluber"). This ground of rejection with respect to claims 1-15, 19-26, 37, 43-45, 48-50, 52, 53, 67, 68, 79, and 82-88 is respectfully traversed.

Claim 1 is directed to a prosthetic device for use with a hip replacement prosthesis that includes an acetabular cup assembly to be fastened to a patient's pelvis and a femoral stem to be fastened to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball

joint type coupling, the prosthetic device comprising: a semiannular augment to be mounted approximate to a rim of an acetabular cup assembly of a hip replacement prosthesis, wherein the semiannular augment assists in improving stability of a ball joint type coupling by increasing the height of a portion of the rim of the acetabular cup, at least temporarily, between the acetabular cup assembly and a femoral stem of the hip replacement prosthesis while allowing rotational and angular movement between the acetabular cup assembly and the femoral stem, the semiannular augment being formed from an augment material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials, and wherein the augment material is supplemented with an agent to promote the formation of scar tissue.

Concerning claim 1, the Office action alleges that one skilled in the art would understand that the PLLA disclosed in Kluber would transform into scar tissue and one skilled in the art would know to utilize other materials or combinations "because they would have performed equally well and wherein the time of resorbability could be controlled." However, Kluber does not disclose controlling the resorbability of the PLLA material, nor discloses providing an additive to promote the formation of scar tissue, nor discloses using a combination of biologic and biologically absorbable materials. These omissions of Kluber are not addressed by the Office action. Instead, the conclusions of the Office action as to what would have been obvious is premised entirely on Applicant's novel disclosure and is paramount to saying every combination is obvious. But such a conclusion is not supported by precedential law.

The generic conclusions recited in the Office action as to obviousness have been consistently overturned by the courts.

> Slight reflection suggests, we think, that there is usually an element of 'obviousness to try' in any research endeavor, that it is not undertaken with complete blindness but rather with some semblance of a chance of success, and that patentability determinations based on that as the test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of 'research.'

In re Tomlinson, 363 F.2d 928, 931 (C.C.P.A. 1966). More recently, the Federal Circuit overturned generic rejections on obviousness grounds where the examiner and the Board failed to discuss the specific limitations at issue in rejecting claims on obviousness grounds.

> We agree with appellants that the Board's ground of rejection is simply inadequate on its face. The Board sustained the examiner's very general and broad conclusion of obviousness based on his finding that "[t]he use of grammar is old and well known in the art of speech recognition as a means of optimization which is highly desirable." Aug. 7, 1996 Office Action at 5; accord Decision on Request for Rehearing at 6. Although this statement is likely true, it fails to address the [other] limitations of claim 11. While the examiner's statement generally addresses the use of grammar, it does not discuss the unique limitations of extracting, modifying, or processing the grammar to interact with hypermedia sources. The Board's decision is not supported by substantial evidence because the cited references do not support each limitation of claim 11.

In re Thrift, 298 F.3d 1357, 1366 (Fed. Cir. 2002). *In re Thrift* is clearly on point to the instant grounds of rejection and mandates a revocation of these grounds or at the very least a supplementation of the record no longer premised on unspecified disclosures. Moreover, just because the elements of the claimed invention are found the prior art does not render the invention *per se* obvious.

> Most inventions arise from a combination of old elements and each element may often be found in the prior art. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. In practice, this requires that the Board "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious." This entails consideration of both the "scope and content of the prior art" and "level of ordinary skill in the pertinent art" aspects of the *Graham* test. (internal citations omitted)

In re Kahn, 441 F.3d 977, 986 (Fed. Cir. 2006).

The reliance of the Office action on the M.P.E.P. to somehow overcome the absence of any comparison between the prior art and the claims at issue is also

unavailing. Instead of addressing the limitations recited in the claims, the recitation of the Office action concentrates on the motivation to modify a prior art reference by citing M.P.E.P. § 2144.04 IV. But the discussion in this section of the M.P.E.P. does not support the position recited. M.P.E.P. § 2144.04 IV (A) indicates that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device, and such a prior art device having the claimed relative dimensions would not perform differently, the claimed device is not patentably distinct from the prior art device, citing *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338 (Fed. Cir. 1984). However, the *Gardner* case is not on point with respect to Applicant's claims.

Applicant's claims are distinguishable over Kluber and the *Gardner* case for multiple reasons. First, unlike the *Gardner* case, Applicant's claims include limitations not disclosed in Kluber that are not dimension specific. Second, Applicant's invention performs differently than the luxation ring disclosed in Kluber because Kluber's ring is a single device that unnecessarily restricts certain directions of movement that are not required to be inhibited in order to inhibit dislocation. Kluber's disclosure says nothing about providing a physician with flexibility to use a range of augments to inhibit dislocation. Applicant's invention also includes separate functionality as to flexible absorption rates and encompasses many more materials and combinations of materials than are discussed or envisioned by Kluber.

Finally, the Office action also cites M.P.E.P. § 2144.04 V (D) for the proposition that anything in the prior art can be considered separable and, thus, the ring of Kluber is an obvious variation of Applicant's augments. But this is not a correct interpretation of M.P.E.P. § 2144.04 V (D). Instead, this M.P.E.P. section only applies to separate, distinguishable components that are mounted to one another. The issue in *In re Dulberg*, 289 F.2d 522, 523 (C.C.P.A. 1961), which is the case cited by this M.P.E.P. section, was whether it was obvious to have a removable cap on a lipstick container, where the prior art taught the cap as a separate part of the lipstick container, but where the cap was not able to be manually removed. This example is in stark contrast the disclosure of Kluber. Unlike the prior art in *In re Dulberg*, Kluber does not teach one that the luxation ring is really fabricated from distinct multiple pieces that could somehow be removed from one another. Instead, the only rational interpretation of Kluber is of a single, uniform ring.

Consistent with this conclusion, Kluber does not disclose a luxation ring comprised of a number of individual parts, or even how the parts would be assembled or disassembled, presuming a disclosure of individual parts for arguments sake. One skilled in the art would have no basis to break the luxation ring of Kluber into pieces, unlike the example of *In re Dulberg*.

Claims 82-88 provide an exemplary claim set for which no substantive explanation is provided in the Office action as to where in Kluber or in any other art made of record the limitations at issue are disclosed. Claim 82 is directed to a restraining device for, at least temporarily, promoting engagement between at least two of a first prosthetic joint component, a second prosthetic joint component, a first bone component, and a second bone component, wherein the restraining device is comprised of a restraining material including at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials, wherein the restraining device is to be mounted approximate at least one of the first prosthetic joint component and first bone component to provide a raised curb that allows angular movement between at least two of a first prosthetic joint component, a second prosthetic joint component, a first bone component, and a second bone component, and does not entirely circumscribe at least one of the first prosthetic joint component, the second prosthetic joint component, the first bone component, and the second bone component, wherein the raised curb arcuately extends 90 degrees or less about at least one of a first prosthetic joint component, a second prosthetic joint component, a first bone component, and a second bone component.

No indication is provided in the Office action where Kluber discloses a raised augment arcuately extending 90 degrees or less. In fact, Kluber only discloses rings that extend arcuately 210 degrees. The absence of a comparison of the pending claims against the disclosure of Kluber or other prior art of record provides Applicant little opportunity to confront the bases for the conclusions of the Office action. As stated before, Applicant declines to guess as to the bases for the conclusions recited in the Office action, particularly in light of 37 C.F.R. § 1.104 (c)(2), which provides in relevant part:

> When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.

It is respectfully requested that the subsequent Office action explain the claim rejections with particularity if the instant grounds are not withdrawn.

Claim 84, which depends from claim 82, further requires that the extra cellular matrices (ECMs) include at least one of: porcine small intestine submucosa (SIS); xenogeneic small intestine submucosa (xSIS); urinary bladder submucosa (UBS); laminated intestinal submucosa; and glutaraldehyde-treated bovine pericardium (GLBP). No indication is provided in the Office action as to where in Kluber it is purportedly disclosed that the extra cellular matrices include one or more of the following.

Claim 87, which depends from claim 82, further requires that the restraining material is adapted to be substantially absorbed and replaced by scar tissue within approximately 6 months after implantation. No indication is provided in the Office action as to where in Kluber this limitation is purportedly disclosed.

Claim 88, which depends from claim 82, further requires that the restraining material is supplemented with an agent to promote the formation of scar tissue. No indication is provided in the Office action as to where in Kluber this limitation is purportedly disclosed.

In sum, Applicant is entitled to a patent unless the Examiner can find prior art to support the grounds of rejection. Applicant respectfully submits that no *prima facie* case of obviousness has been presented that would negate allowance of the pending claims. Even if such a case were to exist, the grounds for such a case are required to be discussed in sufficient detail that Applicant does not have to guess as to the bases. Applicant is earnestly attempting to advance prosecution, but feels inhibited from doing so until the grounds of rejection are better explained. Reconsideration and withdrawal of the rejections of record for claims 1-15, 19-26, 37, 43-45, 48-50, 52, 53, 67, 68, 79, and 82-88 are respectfully requested.

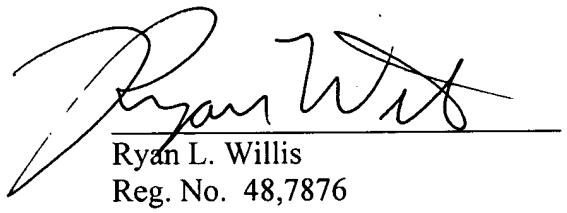
Conclusion

In light of the foregoing, it is respectfully submitted that claims 1-15 and 17-90, now pending, are patentably distinct from the references cited and are in condition for allowance. Reconsideration and withdrawal of the rejections of record are respectfully requested.

The Commissioner for Patents is hereby authorized to charge any additional fees that may be required by this paper, or to credit any overpayment to Deposit Account 50-3072.

In the event that the Examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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